Biotechnology Notes

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Biotechnology Notes, *a compilation of agency activities, news events, and upcoming meetings, is prepared for members of the U.S. Department of Agriculture's (USDA) Committee on Biotechnology in Agriculture (CBA) by USDA's Office of Agricultural Biotechnology (OAB).*

INSIDE USDA

USDA POSTPONES ABRAC DISCUSSION OF ORGANIC STANDARDS

USDA's Agricultural Biotechnology Research Committee (ABRAC) will not be discussing biotechnology and organic food production at its meeting in Arlington, VA, December 16-17. However, ABRAC may discuss the issue at a meeting next year. The recommendation to postpone discussion was made by USDA's Biotechnology Council and implemented by the ABRAC executive secretary. For more details, call Alvin Young, ABRAC executive secretary, at 703-235-4419; Fax: 703-235-4429.

USDA'S NOTIFICATION PROCESS: EIGHT MONTHS LATER

On April 30, 1993, USDA's Animal and Plant Health Inspection Service (APHIS) put into place a notification process for field testing genetically engineered plants. The new system was intended to streamline and economize the regulatory burden placed on the research community, based on APHIS' extensive experience reviewing permit applications and monitoring safety data at over 1,500 field release sites. Going the notification route meant researchers could introduce specific crops under certain conditions without having to complete lengthy permit applications. Now, 8 months later, we ask the question: Has the notification process lived up to its expectations?

"You can't shuffle the paper fast enough," responded Arnold Foudin, Deputy Director of Biotechnology Permits in APHIS' Biotechnology, Biologics, and Environmental Permit (BBEP) office. BBEP has already approved 200 applications under the new system, and another 100 are pending. Foudin said he expects to process between 600 and 1,000 by year's end, and he anticipates issuing 2,000-3,000 notifications in 1994. (See graph on page 8.)

Of the six crops that qualify for the notification process -- corn, cotton, potatoes, soybeans, tobacco, and tomatoes -- corn tops the list as the one most often field tested under the new process.

The dramatic increase in requests for notification permits means that significantly fewer people need to apply for a standard permit. In the last 6 months, BBEP has only issued 30 permits for release. Normally, 320 would have been granted, based on 1992's numbers. Another trend is the complexity of genetic change of the crop being field tested. Foudin said he is now seeing many more innovative constructs.

BBEP has begun supplying quarterly reports to states notifying them of upcoming field tests. Soon, these reports will be accessible electronically to the public. BBEP is also contemplating an expansion of the notification process to include interstate movement. To learn more about the notification process, please call Foudin at 301-436-7612; Fax: 301-436-8669.

A MEETING OF THE MINDS

About 40 researchers, policy makers, and industry representatives met at a retreat November 19 in Beltsville, MD to discuss the future of biotechnology research funding and to come up with a strategic plan for agricultural biotechnology. They spent a half day discussing research activities at USDA agencies, at agricultural biotechnology companies, and on university campuses.

The Federal perspective on agricultural research was given by Gerald Still (USDA/Agricultural Research Service (ARS)), James Slavicek, USDA/Forest Service, and Vern Pursel, USDA/ARS. The industry view was presented by Robert Wilbur, American Cyanamid; Rob Horsch, Monsanto; and Gerald Messerschmidt, DNX. Speaking from an academic point of view were Hector Flores, Penn State University; Chris Somerville, Michigan State University; Ian Sussex, University of California, Berkeley; and Nancy Green, Auburn University.

The retreat was co-sponsored by the Office of Agricultural Biotechnology (OAB), the National Science Foundation, and the National Agricultural Library. Participants included members of the Agricultural Working Group, which reports to the Biotechnology Research Subcommittee of the Federal Coordinating Council for Science, Engineering and Technology. The Working Group plans to meet again to continue the dialogue and to prepare a strategic document on the application of biotechnology to agriculture. For more details, please call Charles Lewis at 703-235-4419; 703-235-4429.

BACK FROM CHINA

A team of U.S. biotechnology experts recently returned from a 2-week visit to China as part of a U.S.-People's Republic of China Scientific Exchange Program. They visited 13 institutes in four cities, examining Chinese plant biotechnology research. The team was impressed with a large number of undergraduate and graduate students interested in agricultural biotechnology and with the spirit of innovation with which they approached their work. Some of the approaches and techniques used are unique to China and are largely unknown in the rest of the world.

Some examples include an ultra-sonification method used to transform undifferentiated corn plant tissue. This process breaks the cell walls of callus tissue, permitting DNA uptake without relying on protoplast culture. Another project involves genetically engineered cotton which was transformed with DNA from wild cotton relatives. The DNA was injected into the pollen tube of field grown plants.

Some of the genetically engineered crops being field tested in China include rice, maize, cotton, barley, soybeans, peanuts, alfalfa, grapes, tomatoes, and tobacco. China currently does not have a formal oversight procedure for reviewing the safety of field tests of genetically modified plants, but draft guidelines have been prepared and the Chinese are studying a number of different "models", including U.S. Government regulations. For more details about the trip, please call Martha Steinbock at 510-987-0069.

NEWS AROUND THE NATION (AND THE WORLD)

FDA APPROVES BST

On November 5, the Food and Drug Administration (FDA) announced approval of the new animal drug sometribove, a recombinant bovine somatotropin (BST) product used to increase milk production in cows. Monsanto Co. of St. Louis, the drug's sponsor, has agreed to conduct a post-approval monitoring program that includes a 2-year tracking system of milk production and drug residues in 21 top dairy states. Monsanto said it will periodically compare the amount of milk discarded because of residues prior to approval versus the amount discarded after the approval OF BST. The monitoring program also includes a reporting system to monitor all BST use and follow up on all complaints. The use of sometribove in 24 commercial dairy herds will be monitored for mastitis, animal drug use, and the resulting loss of milk.

FDA's conclusion that BST is safe for humans has been affirmed by scientific reviews in the past several years conducted by the National Institutes of Health, the Congressional

Office of Technology Assessment, drug and regulatory agencies of Canada, the United Kingdom and the European Community.

FDA said it will not require milk produced from BST-treated cows to be labeled, saying the agency lacks a basis under its statutory laws to require special labeling. Food companies, however, may voluntarily label their products provided the information is truthful and not misleading. Sometribove will be marketed under the trade name Posilac. For more details about FDA's decision, please call Susan Cruzan at FDA at 301-443-3285.

A FISH SWIMS IN BALTIMORE

A state-of-the art aquaculture research center inside a warehouse in downtown Baltimore? It's hard to believe but true as confirmed by several hundred spectators and dignitaries who attended the grand opening November 19.

The Aquaculture Research Center (ARC) is housed in a green warehouse and contains more than 52 tanks filled with a variety of fish used in research. It is a state-of-the art facility with sensitive biofiltration and recirculation systems. There, scientists employ many different laboratory techniques, including biotechnology, to improve aquaculture. They are now developing methods to induce spawning of fish year-round, developing new lines of commercially farmed fish, regulating the growth and development of fish, and developing new diagnostic, therapeutic, and drug-delivery methods to control and eliminate disease. Rockfish, blue crabs, oysters, sea bass, and other species important to the State of Maryland will be the major foci of study. Companies are encouraged to work with ARC researchers. For more details about the facility or its projects, please call 410-783-4890.

SCIENCE PUBLICATIONS NOW ONLINE

Bioline Publications of the United Kingdom has set up an electronic communications system using Internet that is intended for researchers. Journals, newsletters, technical reports, abstracts, etc. will be loaded onto the system for easy browsing. Readers will have to subscribe to the service and to the publishers of commercial journals to receive the full text and graphics of the documents of interest. For further details send an e-mail message to: bio@biostrat.demon.co.uk; or write to Bioline Publications, Stainfield House, Stainfield, Bourne, Lincs PE10 ORS, UK. Phone: +44 778 570618; Fax: +44 778 570175.

BIOTECH FOOD ORDINANCE RESCINDED

According to a Biotechnology Industry Organization (BIO) memo, on November 5 the Chicago City Council rescinded an ordinance which would have required posting of the

following sign next to genetically modified foods: "This Food Product Has Been Genetically Engineered". For more details call Dick Godown at BIO at 202-857-0244.

READ ABOUT PATENTING BIOTECHNOLOGY IN CANADA

The Patent and Trademark Institute of Canada has issued a special edition of the Canadian Intellectual Property Review which focuses only on papers written about biotechnology. For more details write to the Patent and Trademark Institute of Canada, PO Box 1298, Station B, Ottawa, Ontario K1P 5R3; or call 613-234-0516; Fax: 613-234-0671.

MICROBES AND BIOTECHNOLOGY: TIER TESTING WORKSHOP

A workshop to develop ecological tier testing schemes for microorganisms used in biotechnology will be held at the Rosslyn Westpark Hotel in Arlington, VA, January 11-13, 1994. Key findings and recommendations from the workshop will be considered by the Environmental Protection Agency and Environment Canada as they develop guidance for using genetically engineered microorganisms for bioremediation, biomining, mineral leaching, coal transformations, desulfurization of petroleum, oil recovery, biomass conversion, fuel production, waste treatment, nitrogen fixation, and closed system fermentation for the production of enzymes or specialty chemicals.

The workshop is jointly sponsored by EPA and the Commercial Chemicals Branch of Environment Canada. For more information, call Lou Borhi, Clement International Corporation, at 703-934-3255 or Gwen McClung at EPA at 202-260-1273.

HIGH LEVEL COUNCIL NAMED IN CALIFORNIA

California Governor Pete Wilson has established the Governor's Council on Biotechnology, which becomes effective January 1, 1994. The purpose of the Council is to advise the Governor and his staff and recommend actions that encourage the growth of biotechnology in California. It will consist of 24 members, meet quarterly, and disband one year later, unless extended by Executive Order. For more details, call Wes Ervin at 916-324-8104.

IN CASE YOU WEREN'T THERE

■ Harry Kuiper, head of the Department of Risk Analysis and Toxicology at the State Institute for Quality Control of Agricultural Products in The Netherlands presented a seminar at USDA, November 10, on the safety evaluation of a tomato that has

incorporated the gene coding for a BT natural toxin. He said the BT tomato will probably be the first genetically modified product to be marketed in Europe. The evaluations used both in vivo and in vitro studies. The former included work using rats, rabbits and monkeys. Based on these studies, Kuiper concluded that the BT protein did not bind to receptors in the digestive tract of the animals and that there was no evidence of systemic toxicity. In vitro studies showed the protein is broken down under conditions similar to those of the mammalian digestive tract. Kuiper said the Institute wants to use advanced analytical technologies to determine any composition changes as a possible result of gene insertions. Such changes could have a major affect on the safety of the product. For more information about this research, call Harry Kuiper at 31-8370-75400; Fax: 31-8370-17717.

■ The impact of biotechnology on northern California agriculture was one of the panel sessions at a conference in Chico, CA, November 18 entitled "Agricultural Issues and Outlook." It was sponsored by California State University, the Bank of America, and the Chico Regional Commercial Banking. The panel projected that agricultural biotechnology will be an increasingly significant factor in the future of agriculture in Northern California, which many claim is the birthplace of biotechnology. Panelists noted the diversity of ag production in the State, which includes a large share of the nation's horticultural and specialty crops. For more information about the conference, call Loren Parks at 916-898-5733; Fax: 916-898-4675.

NEW PUBLICATIONS

■ Scientific Annual Report 1992. Edited by J. H. Walsdorff. Published by GBF-National Research Center for Biotechnology Ltd., Mascheroder Weg 1, D-38124 Braunschweig, Germany; Tel: 05-31-6181-0; Fax: 49-531-6181-515.

■ "Biodiversity: Saving Species with Biotechnology", by Dennis Avery." A briefing published by Hudson Institute. To order write to Hudson Institute, Herman Kahn Center, P.O. Box 26-919, Indianapolis, IN 46226; or call 317-545-1000.

■ *Chinese Biotechnology Directory*. An English language publication that contains an overview of government policy, industry, science, intellectual property, etc. For more details about ordering, write to Han Communications, P.O. Box 71006, Wuhan, Hubei, 430071, China; Fax: 27-718343.

■ Minutes of the USDA's Agricultural Biotechnology Research Advisory Committee meeting, June 29-30, 1993. Call 703-235-4419; Fax: 703-235-4429.

■ "Biotechnology, Genetic Engineering and Society: Monograph Series III," by George Kieffer. Published by the National Association of Biology Teachers, 1987. For information about ordering this publication, please call NABT at 703-471-1134.

■ *North Carolina's Biotechnology Work Force.* Report based on a survey to assess the employment needs of North Carolina's biotechnology community. April 1993. To receive a copy, call Corinthia Scurlock at 919-541-9366.

■ "Food Safety and Quality: Innovating Strategies May be Needed to Regulate New Food Technologies." (GAO/RCED-93-142). Copies of the report are available from the U.S. General Accounting Office, P.O. Box 6015, Gaithersburg, MD 20884-6015; or call 202-512-6000.

UPCOMING MEETINGS

Dec. 9-10: "Herbicide Resistance Workshop." Edmonton, Alberta, Canada. Sponsored by Environmental Centre, Alberta Agriculture, Food and Rural Development, and the Crop Protection Institute. For details call Branca Barl at 403-362-3391.

Dec. 16-17: Meeting of USDA's Agricultural Biotechnology Research Advisory Committee. Arlington, VA. For details call OAB at 703-235-4419; Fax: 703-235-4429.

Jan. 24-25: "Genetically Engineered Animal Models and their use in Therapeutic Development." San Diego, CA. Call 508-481-6400; Fax: 508-481-7911.

Jan. 24-27: International Plant Genome II Conference. San Diego, CA. For details call 212-643-1750.

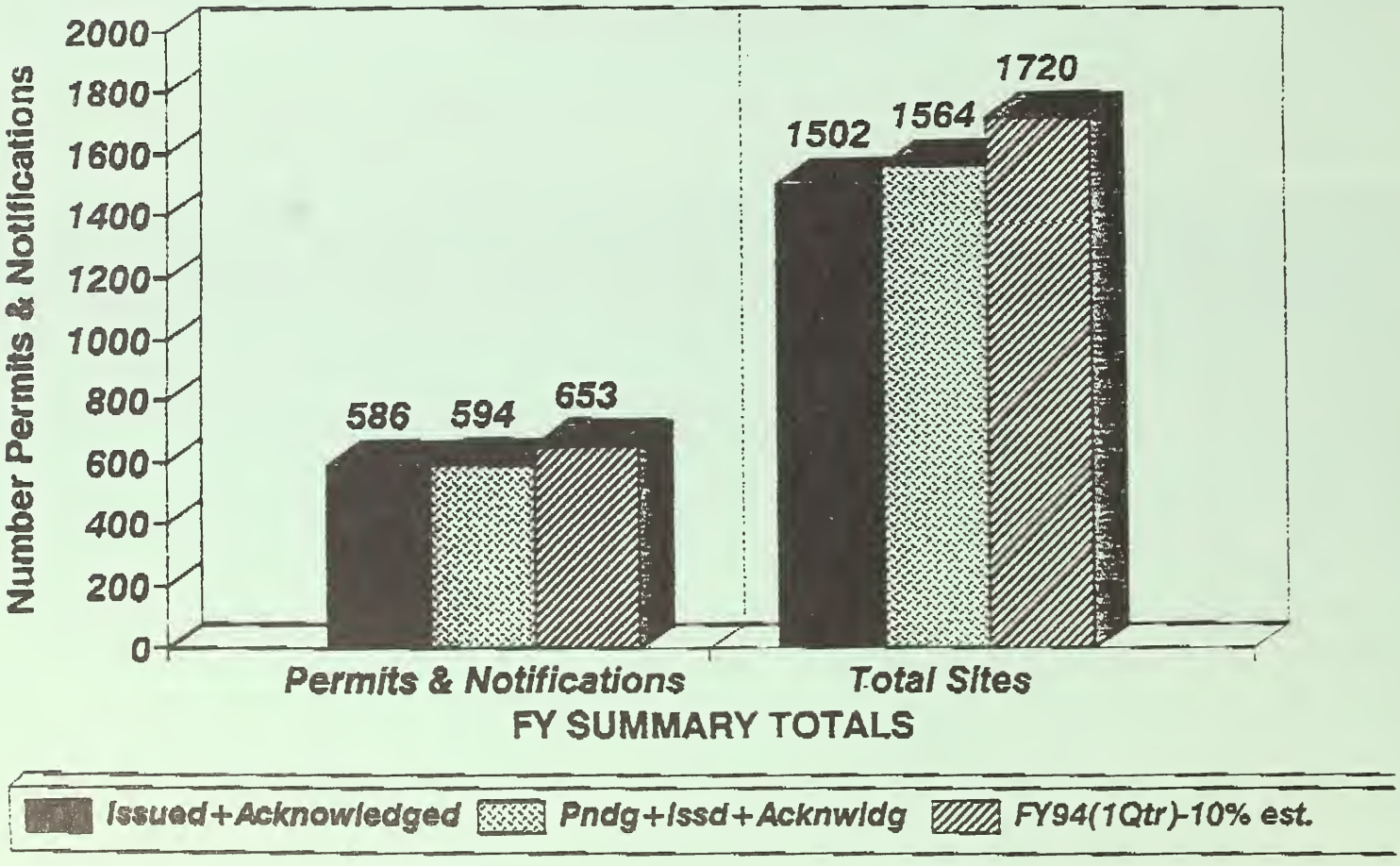
Jan. 24-27: BioEast '94. Washington, DC. Sponsors include *Genetic Engineering News.* For details call 301-652-3072; Fax: 301-652-4951.

Feb. 7-11: "International Conference on Gene Mapping in Terrestrial and Aquatic Vertebrates." Oslo, Norway. For details write to the Norwegian College of Veterinary Medicine, Department of Animal Genetics, Att. Oystein Lie, Box 8146, Dep., N-0033 Oslo, Norway.

Feb. 10-11: Southeast University/Industry Technology Transfer Conference. Orlando, FL. Co-hosted by Duke University Medical Center and the Southern Research Institute. For details call Lucy Malone at 615-366-0679; Fax: 615-366-0695.

April 20-21: Fourth New England Animal Biotechnology Symposium. Storrs, CT. Call 203-486-0861; Fax: 203-486-1072.

BIOTECHNOLOGY PERMITS
RELEASE PERMITS ISSUED AND NOTIFICATIONS ACKNOWLEDGED
FY 1988 - FY 1993
(TO DATE - SEPTEMBER 30, 1993)



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